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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/418,887 10/15/99 COHEN

M 5967.US.D1

EXAMINER

023492
ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
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ABBOTT PARK IL 60064-6050

HM22/0209

TRAN, M
ART UNIT

PAPER NUMBER

1642
DATE MAILED:

02/09/01

Please find below and/or attached an Office communication concerning this application or
proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.

09/418,887

Applicant(s)

COHEN ET AL.

Examiner

MAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

This application filed on October 15, 1999, is a Divisional of application 08/946,869 filed on October 8, 1997 from which patent US 6,110,675 was issued on August 29, 2000, which is a Continuation-in-Part of application 08/727,688 filed on October 8, 1996 from which patent US 5,919,638 was issued on July 6, 1999.

Claims 1-9 were cancelled as entered by Paper #2 and Claims 10-20 are pending.

Election/Restrictions

1. Applicant's election without traverse of species of SEQ ID NO:9 in Paper No. 4 is acknowledged.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. Claims 18 and 20 recite "a composition of matter comprising a PS112 polynucleotide" and a gene, respectively. Both of these claims read on non-statutory subject matter. The addition of the word "isolated" or "purified" to the claims will obviate this rejection.

3. Claims 10-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

The asserted utility is to detect, diagnose, and treat diseases associated with prostate cancer. PS112 gene alleged to be associated with prostate cancer (pg. 10, lines 30-35). It was disclosed in the specification that the PS112 gene was discovered by constructing cDNA libraries from tissues and ran against known EST databases and found the sequence to be novel from known genes (pgs. 51-52, bridging paragraph). It was alleged that this gene is associated with tumors and can be used as a marker for prostate cancer. However, it was noted in Example 1C that when the sequence was compared to the database, it was found to be prevalent in prostate tissue but does not disclose whether expression of this gene was specific for diseased prostate tissues associated with prostate cancer or if the gene was expressed in all tissues of the prostate normal and diseased. In addition, Figure 3B also showed that a Northern of PS112 also showed that normal prostate tissues expressed the gene. Table 1 (pg. 58) also indicated that a positive reactivity to this gene was prevalent in only 2/5 prostate diseased tissues. Therefore, these combined teachings have not showed a distinct association of the PS112 gene with prostate cancer.

From what is disclosed by the specification, it is not clear what the asserted utility is for PS112 and how it may be related to prostate cancer or diseases of the prostate because the specification has not shown how PS112 is related to prostate cancer. Because of the lack of teaching and direction as to how PS112 is associated with prostate disease and prostate cancer, the skilled artisan would be invited to elaborate a functional use for the disclosed polynucleotide.

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4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-20 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The specification has not shown how the PS112 gene is associated with prostate cancer, therefore, one skilled in the art would not know how to use it to diagnose or treat prostate cancer using the claimed polynucleotide.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite PS112. It is not clear what this is. It appears to be a lab designation for a gene and does not convey the properties of the term and does not clearly define the claimed product. Different labs will use similar designations to mean different products. Further clarification is required.

The claims also recite "at least 50% identity" but does not clarify to what the identity refers. Polynucleotides can have 50% sequence identity but does not share the same characteristics of the claimed nucleotide. It is not clear what applicant is claiming as the instant invention. Further clarification is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10-20 are rejected under 35 U.S.C. 102(b) as anticipated by Matsubara et al (EP 679716A1, 1995) or Hillier et al (EMBL N31660, 1995) or Hudson et al (EMBL G22461, 1995).

Claims 10-20 are drawn to a polynucleotide or fragments thereof with at least 50% identity to SEQ ID NO:9. Matsubara et al taught a polynucleotide sequence which is 100% identical to SEQ ID NO:9 at positions 1-116. Hillier et al taught a polynucleotide sequence which is 100% identical to SEQ ID NO:9 at positions 1-412. Hudson et al taught a polynucleotide sequence which is 100% identical to SEQ ID NO:9 at positions 1-271. Therefore, any of these above references anticipates the claims as drawn to fragments of SEQ ID NO:9.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No.

5,919,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are both drawn to a polynucleotide of SEQ ID NO:9 and method of making said nucleotide. Although claims 10 and 19 recites a test kit useful for detecting PS112, the scope of the claim is drawn to the polynucleotide of SEQ ID NO:9 which is still covered by patent number 5,919,638. The way in which the tissues are collected, as recited in claim 19, are not unique in any way different from standard procedures for tissue collection and not patentably distinct and given little weight on the scope of the claim.

9. No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mau Tran whose telephone number is 703-605-1165. The examiner can normally be reached on Monday-Friday from 8:00 a.m. – 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. Any inquiry of a general

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nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Mau Tran, Ph.D.
Patent Examiner, Art Unit 1642
February 5, 2001


GEETHA P. BANSAL
PRIMARY EXAMINER